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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/787,307

02/26/2004

Brian C. Case

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BUCHANAN INTELLECTUAL PROPERTY OFFICE LLC

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EXAMINER

STROUD, JONATHAN R

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/787,307	Applicant(s) CASE ET AL.	
	Examiner JONATHAN STROUD	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 37 is/are pending in the application.
- 4a) Of the above claim(s) 1-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This final office action is in response the arguments, filed 12/30/2009. The amendments necessitated the new grounds of rejection; thus, finality of this office action is proper.

Response to Arguments

1. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.
2. Applicant's amendments have substantially changed the scope of the claimed method of claim 37. By amending the claim to determine the location of the imageable structure relative to the distal end of the delivery apparatus, applicant has altered both the consideration and interpretation of the previously filed claim, which read "determine a location of the imageable structure relative to at least one of the valve prosthesis and the delivery apparatus. Further, applicant now determines the orientation of the entire prosthesis, not just the orifice. Both amendments require a new search and consideration.
3. Applicant's primary inventive concept appears to be the "circumferential orientation" applicant discussed on page two of the specification. While this is not claimed at the present time (but rather applicant claims using indicia to determine the longitudinal orientation), applicant's attention is directed at Peckham 2005/0113686, which discloses a means for using visual indicia to control the rotational orientation of a stent.

Claim Rejections - 35 USC § 112

Art Unit: 3774

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 37 recites the limitation "and the packaging material thereof" in paragraph

4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 37 is rejected under 35 U.S.C. 103(a) as obvious over Healy 6,074,419, further in view of the patent application 2004/0006380 to Buck.

Re claim 37, Healy discloses a stentless heart valve 104 with indicia 28 indicating the location of the device, the circumferential orientation, and the ascending and descending end/orientation.

Healy teaches using the indicia to orient and deliver said valve into the heart.

Healy fails to positively disclose the use of a delivering such a device via a catheter delivery system (well known in the art).

Re claim 37, Buck teaches a stent delivery system and associated method (see claims 33 and 34) designed to verify the orientation of a stent within a delivery system, comprising:

A stent with a sleeve coupled to a moveable member and comprising a jacket, where the jacket includes one of visible and tactile indicia, see [para. 0020]; see *a/so* fig. 6 element 116, in a length corresponding to the length of the stent ... being co-incident with the distal end of the sleeve (and thus providing indicia of the descending orientation), and

Using an imaging device [pars. 0007] to image the device (which indicates the descending orientation via the indicia), closest to the distal end of the orifice of the stent.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Healy, further in view of Buck, in order to 1) utilize the indicia (See *Healy*, col. 5 ll. 1-25; ("The indicia is used during the implantation procedure to provide the surgeon or attending staff with information which will aid in the procedure. This simplifies the implantation process ... [which] proceed[s] at a faster rate thereby shortening the length of time needed to perform surgery. Thus, the invention provides more accurate implantation which requires a shortened surgical procedure.")) and 2) to accurately deploy the device (See *Buck*, abstract).

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over the patent application 2004/0006380 to Buck, further in view of the U.S. patent application to Bailey 2001/0021872.

Re claim 37, Buck teaches a stent delivery system and associated method (see claims 33 and 34) designed to verify the orientation of a stent within a delivery system, comprising:

Art Unit: 3774

A stent with a sleeve coupled to a moveable member and comprising a jacket, where the jacket includes one of visible and tactile indicia in a length corresponding to the length of the stent ... being co-incident with the distal end of the sleeve (and thus providing indicia of the descending orientation), and

Using an imaging device [pars. 0007] to image the device (which indicates the descending orientation via the indicia), closest to the distal end of the orifice of the stent.

Buck fails to teach applying this method to deploy a heart valve/stent apparatus in a similar fashion.

However, it is well-known in the art that methods of deploying heart valves (with stents) and stents are known in the art as taught by the Bailey.

Further, Bailey teaches markers on a valvular stent structure specifically for the purposes of valve orientation [para. 0055], and mounting that valve onto a catheter system and deploying it [catheter para. [0068-0074]], including a sheath and a downward or descending approach.

It would have been obvious to modify the teachings of Buck, which teaches a method of including an indicia on an apparatus and using that indicia to orient the delivery of that stent, with the teachings of Bailey, which teach applying markers to a valvular stent structure to determine valve orientation, mounting that valve onto a catheter, and deploying it, for the purposes of better-determining the approach and facilitating the surgery by giving the surgeon more control and means for verifying that the orientation of the valve is correct post-implantation.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,602,241 to Makower, further in view of the U.S. patent application Bailey 2001/0021872.

Re claim 37, Makower teaches a method for delivering an “apparatus” as claimed to the human body using guidance and imaging – claim 63 of Makower - including markers, imaging, and the utilization of an imaging apparatus (claims 65 and 66) to determine positioning and make the surgery easier.

Makower fails to teach that the “apparatus” can be a valve, or applying this method to deploy a heart valve/stent apparatus in a similar fashion.

However, it is well-known in the art that methods of deploying heart valves (with stents) and stents are closely analogous (as shown by the Bailey reference below).

Further, Bailey teaches this, as indicated in the previous rejection, *supra*.

It would have been obvious to modify the teachings of Makower, which teaches a method of including an indicia on an apparatus and using that indicia to orient the delivery of that stent via an external imaging apparatus, and methods of doing so thereof, with the teachings of Bailey, which teach applying markers to a valvular stent structure to determine valve orientation, mounting that valve onto a catheter, and deploying it, for the purposes of better-determining the approach and facilitating the surgery by giving the surgeon more control and means for verifying that the orientation of the valve is correct post-implantation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on 8-4, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3774

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan R Stroud/
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774